

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in November 2013.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-406

Trade Name: NexGard™
Ingredients: Afoxolaner
Sponsor: Merial Ltd.
Approval Date: September 14, 2013
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Chewable tablet
Concentration: Each chewable contains 11.3 mg, 28.3 mg, 68 mg, or 136 mg afoxolaner.
Indications: For the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of American dog tick (*Dermacentor variabilis*) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for 1 month.
Exclusivity: 5 years

21 CFR 520.43

78 FR 66263-66265

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 095-735

Trade Name: Rumensin®
Ingredients: Monensin
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: September 5, 2013

This supplement provides for the reduction in the minimum concentration of monensin in Type C medicated feeds for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers) from 25 to 15 grams per ton.

21 CFR 558.355

78 FR 66263-66265

NADA Number: 141-288

Trade Name: EXCENEL® RTU EZ
Ingredients: Ceftiofur hydrochloride
Sponsor: Zoetis Inc.
Approval Date: September 13, 2013

This supplement provides for a reformulated product for use in swine and cattle, addition of a new route of administration (intramuscular injection) in cattle, change of withdrawal period in cattle, and a 250 mL vial size.

21 CFR 522.313b

78 FR 66263-66265

Sponsor Change

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The following corrections or additions to the list were published in the Federal Register in November 2013.

ANADA Number: 200-555

Previous: Piedmont Animal Health

New Sponsor: Bayer HealthCare LLC, Animal Health Division

Drug Labeler Code: 000859

21 CFR 520.309

78 FR 66263-66265

Patent Additions

NADA Number: 141-258, 141-276, 141-278, 141-280, 141-282, 141-284

Patent number: 8,580,772

Expiration Date: April 30, 2030

Patent Correction

NADA Number: 141-334

Original Patent number: 6,154,946

Corrected Patent number: 6,514,946

Withdrawal of Approval

NADA Number: 007-891

Sponsor: Zoetis Inc.

Trade Name: 3-Nitro®

Ingredients: Roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.530

78 FR 69992-69994

NADA Number: 010-285

Sponsor: Zoetis Inc.

Trade Name: Carb-O-Sep®

Ingredients: Carbarsone

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.120

78 FR 69992-69994

NADA Number: 092-953

Sponsor: Zoetis Inc.

Trade Name: Roxarsone

Ingredients: Roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.530

78 FR 69992-69994

NADA Number: 008-019

Sponsor: Fleming Laboratories, Inc.

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The following corrections or additions to the list were published in the Federal Register in November 2013.

Trade Name: Pro-Gen
Ingredients: Arsanilic acid

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.62

78 FR 70496